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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,177	11/23/2001	George A. Cates	1038-1168 MIS:jb	6952 .

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,177	CATES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-14,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-14,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 3, 5-14, 20 and 21 are pending in the application. The claims were rejected in the prior action, mailed on July 13, 2004. In the Response, filed on October 7, 2004, the Applicant amended claim 3.

2. Because this action raises new rejections, it is being made Non-Final.

Drawings

3. **(New Objection)** The drawings are objected to because The drawing marked as Figure 1 appears to have indicated the claimed composition as "Flu/RSV + PCP." It appears that this should read - - Flu/RSV + PCPP- -. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. **(New Objection)** Claim 3 is objected to because of the following informalities: there is no comma between the last and next to last elements in the list in subpart (b) of the claim. It is suggested that a comma be inserted between the term "attachment (G)" and the phrase "and matrix (M) protein."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained in part)** Claims 3, 5-14, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed immunogenic compositions, does not reasonably provide enablement for such compositions that are effective for the protection of the host against disease caused by RSV. In view of the cancellation of the functional language from claims 3, and 5-14, the rejection is withdrawn from these claims. However, the rejection is maintained against claims 20 and 21 which still read on a method for the immunization of a human host against RSV.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(New Rejection)** Claims 3, 5-14, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is treated as representative. This claim defines a multi-valent immunogenic composition comprising an "immunoeffective amount" of both an anti-RSV immunogenic composition, and a non-virulent influenza composition. It is unclear what is meant by an "immunoeffective amount" of these compositions. It is unclear how this amount is determined. It is suggested that the phrase "an immunoeffective amount of" be removed from subparts (a) and (b) of the claim, and from claim 20. I.e., it is suggested that claim 3 be amended such that the claim is amended to read on a composition comprising

- - (a) a mixture of purified fusion (F), attachment (G), and matrix (M) protein of RSV,

(b) a non-virulent influenza virus preparation, and- - .

Clarification of the claim language is required.

9. **(New Rejection)** Claim 3 contains the trademark/trade name "Fluzone®." Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods

associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a component of the claimed immunogenic composition and, accordingly, the identification/description is indefinite. It is required that the claim be amended to identify the claim non-virulent influenza virus preparation by its structure, and provide evidence demonstrating identity between the indicated composition and the Fluzone® influenza virus preparation used in the present application.

It is noted that, because the claims have not been rejected based on unexpected results of the combination of the Fluzone® influenza vaccine, the indicated anti-RSV composition, and PCPP, use of the specific anti-influenza Fluzone® vaccine used in the Examples of the application is required.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **(New Rejection)** Claims 3, 5-14, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S. (U.S. Patent 6,020,182), or Cates PCT (WO 98/02457), in view of the teachings of Payne (Vaccine 16(1): 92-98) or Andrianov (U.S. 5,494,673), and of Huebner (U.S. Patent 5,612,037). The claims have been described previously, as have the teachings of the references.

The Cates references teach an RSV subunit formulation identical to the formulation used as the RSV component of the instantly claimed multivalent vaccine. Cates also teaches that the composition may also comprise an adjuvant, including adjuvants with immunostimulating effects (therefore imparting an enhanced immune response to RSV). Cates U.S. Col. 4, lines 6-24. Finally, Cates also teaches the combination of the RSV vaccine with immunogens against other infections, including immunogens against influenza and that the RSV composition may comprise between 1 and 100 μg of the RSV subunit composition. See, e.g. Cates U.S., columns 11-16 (showing varying amounts of the RSV from 1 to 100 μg compositions). Each of these references also teaches that the disclosed RSV composition may be used with an adjuvant. Cates U.S., column 4, lines 6-24; Cates PCT, page 7, lines 14-34. Among the adjuvants suggested by these references is polyphosphazene. Id. However, Cates references do not teach that the influenza immunogen is the Fluzone® non-virulent influenza virus preparation, or that the polyphosphazene is PCPP.

As indicated in the prior actions, each of Payne and Andrianov teach that PCPP is an effective vaccine, and teach its use in viral vaccines. Huebner describes a commercial inactivated influenza vaccine (FLUZONE®) and its administration in a dose of 5μg. See, Huebner, col. 1, lines 15-18; and col. 7, Table III. For the reasons indicated in the prior actions (see e.g., the Office Action of March 26, 2003), the combination of these references with the Cates references renders the claimed inventions obvious.

Previously, the rejection of the claims was withdrawn on the basis of unexpected results shown by the Applicant in the combination of PCPP, the influenza vaccine Fluzone®, and the indicated anti-RSV composition. However, upon further review, it is noted that the Applicant has

established these unexpected results with only a single combination of these elements comprising 1 μg of the RSV composition, 5 μg of the anti-influenza vaccine Fluzone®, and 200 μg of PCPP. However, the claims are drawn to any combination of these elements wherein the PCPP may be present in any amount, and the immunogenic compositions may be present in at least any of the relative amounts presented in claim 5. There is no demonstration that the same unexpected results would be achieved no matter the relative amounts of the various ingredients used in the composition. I.e., it is not clear that any concentration of PCPP with any concentration of the RSV mixture and any concentration of the anti-influenza Fluzone® vaccine would result in the indicated synergistic results.

Because the withdrawal of the rejection is based on unexpected results, and it is not clear that such results would be achieved by any combination of the respective ingredients regardless of how much of each ingredient relative to the others was used, the rejection is reinstated against the indicated claims.

12. **(New Rejection)** Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S. or Cates PCT, in view of the teachings of Payne or Andrianov, and Huebner, further in view Murry et al. (Hosp. Pract. 32(7): 87-8, 91-4) or Potash (U.S. 5,911,998). Claim 21 is directed to methods of immunizing a human of at least 18 years of age against RSV using the composition of claim 3. The teachings of the cited references have been disclosed in the prior actions. See e.g., the action mailed on March 26, 2003. This rejection is reinstated for substantially the same reasons as indicated with respect to claims 3, 5-14, and 20 in above.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **(New Rejection)** Claims 3, and 5-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 2, 6-16 of U.S. Patent No. 6,309,649 in view of Payne or Andrianov, and Huebner. This rejection is on substantially the same grounds as indicated above with respect to the Cates reference, and as indicated on pages 18-19 of the action mailed on March 16, 2003, except that the teachings of Payne and Andrianov are used in addition to the teachings of the patent with respect to PCPP, and the Huebner reference is used to teach the specific anti-influenza vaccine (Fluzone®) identified in claim 3 as it is currently pending.

15. **(New Rejection)** Claims 3, 5-14, 20, and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9,15-21, and 23 of copending application 10/488,241 (which provides substantially the same teachings as the Cates U.S. reference above) in view of Payne or Andrianov, and Huebner.

This rejection is on substantially the same grounds as indicated above with respect to the Cates reference above.

This is a provisional obviousness-type double patenting rejection.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 2/18/05

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